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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,081	06/20/2003	Alan R. Fritzberg	295.054US1	6899

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EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,081	FRITZBERG, ALAN R.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-35* is/are pending in the application.

4a) Of the above claim(s) *26-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-25 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/14/05; 2/17/05; 8/2/04; 7/19/04, 11/21/03; 9/15/03, 8/4/03;
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 9/26/05 wherein claims 1-13 are canceled and claims 19 and 35 are amended.

Note: Claims 14-35 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to a method of treating a bone associated cancer wherein 153Sm-EDTMP and melphalan are administered as set forth in independent claim 14. in addition, Applicant has claims directed to a composition comprising 153Sm-EDTMP and a radioprotectant as set forth in independent claim 26.

RESPONSE TO APPLICANT'S ELECTION

3. Applicant's election with traverse of Group II, claims 14-25 filed 9/26/05 is acknowledged. The traversal is on the grounds that the Examine has not identified a materially different process or materially different products of the instant invention. This is found non-persuasive because Group II (claims 14-25 and 35) is directed to a method wherein a composition comprising 153Sm-EDTMP and melphalan is utilized. Group III (claims 26-34) is directed to a composition comprising 153Sm-EDTMP and a radioprotectant. First, it is noted that one group is directed to method claims and the other product claims. Secondly, the composition (153Sm-EDTMP and melphalan) of Group II is a different composition from that set forth in Group III. While both Groups II and III use 153Sm-EDTMP, the melphalan which is use in Group II is different from a

radioprotectant. Thus, prior art which anticipates or renders obvious a composition comprising 153Sm-EDTMP and melphalan used in a method of treating bone associated cancer would neither anticipate nor render obvious a composition comprising 153Sm-EDTMP and a radioprotectant because melphalan is a drug commonly used for bone marrow ablation whereas a radioprotectant (i.e., ascorbate or gentisic acid) serves to prevent radiolysis of the radionuclide. Hence, the compositions are distinct and materially different. In addition, it is noted that one group of claims is directed to products and another to method claims. As a result, the restriction requirement is still deemed proper and is therefore made FINAL.

Note: As evidence that Groups II and III are distinct, Applicant is respectfully requested to review the 103 reject below and the cited prior art which while applicable to the claims of Group II, neither anticipate nor render obvious the composition of Group III.

WITHDRAWN CLAIMS

4. Claims 26-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

112 REJECTIONS

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim as written is ambiguous because it is depends upon independent claim 14 which disclosed that the subject does not undergo total body irradiation while claim 16 specifically states that the subject may undergo chemotherapy and *total body irradiation*, chemotherapy, or *total body irradiation*. Thus, clarification is requested.

DOUBLE PATENTING REJECTIONS

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 14-25 and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6, 7, 9, 10, and 12-18 of copending Application No. 11/014,828. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of treating bone associated cancer in a subject wherein 153Sm-EDTMP and a second chemotherapeutic agent is utilized. The claims differ in that 11/014,828 does not limit the second chemotherapeutic agent to melphalan as in the instant invention. However, a skilled practitioner would recognize that melphalan is obvious because in claim 18 of 11/014,828, melphalan is specifically disclosed as the agent that is administered in combination with 153Sm-EDTMP.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

103 REJECTIONS

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 14-16, 18, 19, 23-25, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner et al (WO 91/16075).

Turner et al disclose bone marrow treatments. A subject is administered a labeled bone localizing chelating agent and a cytotoxic pharmaceutical . A possible radionuclide is samarium-153. A possible chelating agent is EDTMP. A possible cytotoxic drug is melphalan (see entire documents, especially, abstract; pages 2-3, bridging paragraph). Melphalan is a drug that may be used alone for bone marrow ablation (page 2, lines 4-5). A preferred embodiment of Turner et al comprises the use of EDTMP labeled with samarium-153 (paged 3, lines 27-28). Total body irradiation is optional. For example, Figure 2 discloses the viability of marrow transplantation after total body irradiation. Figure 1 discloses the platelet concentration in the blood following lethal total body irradiation. Figure 4 discloses the use of 153Sm-EDTMP at a rate of 3.5 GBq *instead* of total body irradiation. In Figure 5, the effect of varying doses of melphalan is disclosed. In Figure 6, survival rate after chemotherapy and/or radiotherapy treatment with melphalan and 153Sm-EDTMP is disclosed. Also, in Figure 6, a control with melphalan alone is disclosed. A sample comprising the samarium and

melphalan, but without marrow transplantation is disclosed as well. Still, in Figure 6, data involving subjects treated with 153Sm-EDTMP, melphalan, and given a marrow transplant at day three is disclosed. In Figure 7, the result of delaying marrow transplant until six days after the commencement of the procedure is disclosed. In this particular case, the procedure commenced with samarium endoradiotherapy and five days later, the cytotoxic compound, melphalan, was administered. Turner et al fail to specifically state the range of melphalan and the range of radiation that may be utilized with their invention.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Turner et al and use doses of about 140 – 200 mg/m2 of melphalan in combination with 153Sm-EDTMP because a skilled practitioner in the art would recognize that depending upon a subject's weight, age, etc., the amount of melphalan needed will vary (it should be noted that Figure 5 of Turner et al disclose the effect of melphalan at varying dose rates on subjects). Hence, since Turner et al discloses the use of 153Sm-EDTMP in combination with melphalan, it would have been obvious to one of ordinary skill in the art at the time of the invention to have a range of melphalan since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 233). Likewise, Turner et al disclose that a subject may be radiated at various dosages. Thus, for the same reasons as why one would be motivated to generate a range and optimize that range for

melphalan, one would be motivated to perform the same routine steps to optimize the radiation that a subject should receive.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1618

December 23, 2005